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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,050	03/22/2004	James E. Kipp	IFT-6019	1570

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EXAMINER

KUGEL, TIMOTHY J

ART UNIT	PAPER NUMBER
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1712

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,050

Applicant(s)

KIPP ET AL.

Examiner

Timothy J. Kugel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/1/04 & 4/28/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

1. Claims 1-8 are pending as filed 22 March 2004. Claim 8 is withdrawn from consideration.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a method for modifying a particle suspension, classified in class 516, subclass 77.
- II. Claim 8, drawn to an apparatus for comminuting particles suspended in a solution, classified in class 137, subclass 896.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used for mixing two fluids without suspended particles.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Michael Mayo on 20 August 2005 a provisional election was made with traverse to prosecute the invention of I, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action.

Claim 8 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

7. Regarding the reference "Gruverman", the information disclosure statement filed 28 April 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The text of the reference is cut-off at the right margin. It has been placed in the application file, but unless the reference has been cited by the examiner on form PTO-892, the information referred to therein has not been considered.

Oath/Declaration

8. A new oath or declaration is required because the residence of inventor Joseph Chung Tak Wong has been amended. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it

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is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Drawings

9. The drawings are objected to because while the drawings filed 3 September 2004 appear to be replacement drawing, they are not labeled as such. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

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requested in correcting any errors of which applicant may become aware in the specification.

11. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

12. The use of the trademark EMULSIFLEX has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Objections

13. Claim 7 is objected to because of the following informalities: Claim 7 recites, "...including a organic compound..." and should recite, "...including an organic compound..." Appropriate correction is required.

Claim Interpretation

14. The claims use the transitional terms includes, including, etc. which have been construed as being synonymous with 'comprising', which is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.
15. The phrase "fluid suspending solid particles" has been construed to be synonymous with "solid particles suspended in a fluid."

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 5 recite the limitation "mixing of at least some of the particles in the first and second streams." It is unclear if this limitation means that the particles suspended in the first fluid stream are mixed into the second fluid stream or if particles from a second source—for which there would be insufficient antecedent basis—are mixed into the first and second fluid streams. For the purpose of examination, the claims were construed to recite, "...mixing of at least some of the particles from the first fluid stream into the second fluid stream."

Claim 3 recites the limitation, "mixing of at least some of the particles in the first stream." It is unclear what this limitation means as the particles are already described as being suspended in the first fluid. For the purpose of examination, claim 3 was

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construed to recite, "...mixing of at least some of the particles from the first fluid stream into the second fluid stream."

Claim 7 recites the limitation "...mixing of the solution of the solvent streams..."

There is insufficient antecedent basis for this limitation in the claim. For the purpose of examination, claim 7 was construed to recite, "...mixing of the solution from the first solution stream with the second solution stream..."

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,221,332 (Thumm).

Thumm teaches a method of dispersions, encapsulations, and emulsions (Column 16 Lines 58-64) comprising moving two or more fluid streams at high velocity and pressure (Column 3 Lines 22-29) each potentially containing solid particles (Column 16 Lines 65-66) such that they enter and meet within a mixer/reactor chamber (Column 3 Lines 53-56 and Figures 2A-2C).

20. Claims 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,314,506 (Midler).

Midler teaches a method of producing a particle suspension comprising impinging jets of a solution of an organic compound in an organic solvent and an anti-

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solvent—including water—such that a high purity stable dispersion results (Column 2 Lines 16-19, Column 4 Line 55 – Column 5 Line 19 and Figures 2 and 3).

Claim Rejections - 35 USC § 103

21. Claims 5-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Emulsifying Cell Operating Manual, Best Emulsifying Equipment International, Midgdal Haemek, Isreal (BEEI) in view of Midler.

BEEI teaches a method of mixing two fluids wherein a first fluid stream and a second fluid stream are moved such that the two streams are mixed to produce stable dispersions (Page 4 ¶1, Page 7¶2) including the use of a Venturi effect to combine the two fluids (Figure 11).

BEEI does not disclose expressly that the first fluid is a solution of an organic compound.

Midler teaches a method of producing a particle suspension comprising impinging jets of a solution of an organic compound in an organic solvent and an anti-solvent—including water—such that a high purity stable dispersion results as detailed above.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use the organic compound and solvent of Midler in the method of BEEI. The motivation to do so would have been to produce a pharmaceutical with high bioavailability (Midler Column 1 Lines 19-21).

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Note that although the reference BEEI is undated, since applicant submitted the reference on the information disclosure statement dated 1 July 2004 it has been construed as admitted prior art.

22. Claims 5-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Midler in view of US Patent 3,685,261 (McIlvaine).

Midler teaches a method of producing a particle suspension comprising impinging jets of a solution of an organic compound in an organic solvent and an anti-solvent—including water—such that a high purity stable dispersion results as detailed above.

Midler does not disclose expressly the use of the Venturi effect to combine the two fluid streams.

McIlvaine discloses a method and apparatus for dispersing two fluids including a Venturi (Column 1 Line 56 – Column 2 Line 15 and Figures 1-6).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use the Venturi of the apparatus of McIlvaine in the method of Midler. The motivation to do so would have been to thoroughly mix and disperse the two fluids (McIlvaine Column 2 Lines 13-15).

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication 2002/0176935 (Kipp '935), US Patent Application Publication 2003/0031719 (Kipp '719) and US Patent Application Publication

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2003/0044433 (Werling '433) which are X-type references cited on the International Search Report for PCT/US2004/009242, which is a child of the instant application, teach methods of preparing submicron suspensions from one or more fluids comprising solid particles, but the mixing means taught are mechanical stirrers, homogenizers and sonicators rather than the shearing due to the movement and positioning of the two streams of fluid.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Kugel whose telephone number is (571) 272-1460. The examiner can normally be reached on 6:30 AM - 4:30 PM Monday - Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

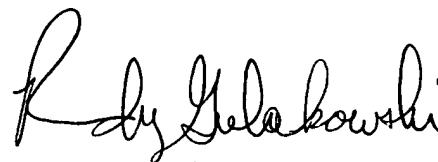
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A handwritten signature in black ink, reading "Randy Gulakowski". The signature is fluid and cursive, with the first name "Randy" and last name "Gulakowski" clearly distinguishable.

RANDY GULAKOWSKI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700